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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,597	12/21/2001	Ian Robert Cottingham	0623.0730002/LBB/BJD	2450
26111	7590	10/21/2003	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC			PRIEBE, SCOTT DAVID	
1100 NEW YORK AVENUE, N.W.			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20005			1632	

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,597	COTTINGHAM ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 20-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-17 and 20-75 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 68-70 and 74, which are directed to fusion proteins, are improper dependent claims that do not further limit the subject matter of the claims from which they depend, which are directed to DNA molecules. They have been grouped according to the subject matter being claimed, rather than the subject matter of the claims from which they depend.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 7, drawn to a method for producing a fusion protein comprising calcitonin and lysozyme in milk of a transgenic non-human mammal, classified in class 800, subclass 7.
- II. Claim 7, drawn to a method for producing a fusion protein comprising parathyroid hormone and lysozyme in milk of a transgenic non-human mammal, classified in class 800, subclass 7.
- III. Claim 7, drawn to a method for producing a fusion protein comprising glucagon and lysozyme in milk of a transgenic non-human mammal, classified in class 800, subclass 7.
- IV. Claim 7, drawn to a method for producing a fusion protein comprising glucagon-like-peptide-1 and lysozyme in milk of a transgenic non-human mammal, classified in class 800, subclass 7.

- V. Claim 7, drawn to a method for producing a fusion protein comprising magainin and lysozyme in milk of a transgenic non-human mammal, classified in class 800, subclass 7.
- VI. Claim 7, drawn to a method for producing a fusion protein comprising histatin and lysozyme in milk of a transgenic non-human mammal, classified in class 800, subclass 7.
- VII. Claim 7, drawn to a method for producing a fusion protein comprising protegrin and lysozyme in milk of a transgenic non-human mammal, classified in class 800, subclass 7.
- VIII. Claim 7, drawn to a method for producing a fusion protein comprising clavainin and lysozyme in milk of a transgenic non-human mammal, classified in class 800, subclass 7.
- IX. Claims 44 and 59, drawn to a fusion protein comprising calcitonin and lysozyme, classified in class 530, subclass 350.
- X. Claim 44 and 59, drawn to a fusion protein comprising parathyroid hormone and lysozyme, classified in class 530, subclass 350.
- XI. Claims 44 and 59, drawn to a fusion protein comprising glucagon and lysozyme, classified in class 530, subclass 350.
- XII. Claims 44 and 59, drawn to a fusion protein comprising glucagon-like-peptide-1 and lysozyme, classified in class 530, subclass 350.
- XIII. Claims 44 and 59, drawn to a fusion protein comprising magainin and lysozyme, classified in class 530, subclass 350.

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- XIV. Claims 44 and 59, drawn to a fusion protein comprising histatin and lysozyme, classified in class 530, subclass 350.
- XV. Claims 44 and 59, drawn to a fusion protein comprising protegrin and lysozyme, classified in class 530, subclass 350.
- XVI. Claims 44 and 59, drawn to a fusion protein comprising clavainin and lysozyme, classified in class 530, subclass 350.
- XVII. Claims 20-27, 65-67, 71-73 and 75, drawn to DNA encoding a fusion protein comprising lysozyme, classified in class 536, subclass 23.4.
- XVIII. Claims 28 and 29, drawn to a transgenic non-human mammal whose genome comprises to DNA encoding a fusion protein comprising lysozyme, classified in class 800, subclass 14.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VIII and IX-XVI, respectively, are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the fusion proteins being claimed could be produced recombinantly from cultured mammalian cells.

Inventions XVIII is related to inventions I-VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case invention XVIII does not require that the fusion protein be secreted into milk, and thus embraces transgenic non-human mammals which cannot be used in any of the claimed methods. Such transgenic mammals could be used for in variety of processes dependent upon effect of the fusion protein on cells or tissues of the mammal. Also, invention XVIII embraces transgenic mammals expressing a lysozyme-fusion protein that does not comprise the peptides of inventions I-VIII.

Inventions XVIII and XVII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination requires only that the fusion protein encoded by the DNA comprise lysozyme and a peptide, whereas the DNA of the subcombination may have a variety of further features, e.g. a promoter (claim 22), or the fusion protein may further comprise a protein leader sequence (claim 23) or a linker sequence (claim 24). The subcombination has separate utility such as production of the fusion protein encoded thereby in cultured cells.

Inventions IX-XVI and invention XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to very different classes of compounds, which are not disclosed as being used together, and have different modes of operation, functions, and

effects. Also, the fusion protein encoded by the DNA of invention XVII embraces fusion proteins other than those of inventions IX-XVI.

Claims 1-6, 8-15, and 32-36 link inventions I-VIII. Claims 16, 17, 30, 31, 37-43, 45-64, 68-70, and 74 link inventions IX-XVI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Should Applicant elect group XVII or XVIII, and add (or amend) claims readable on the elected generic invention wherein the fusion protein comprises one of a recited multiplicity of distinct peptides, as with groups I-VIII or groups IX-XVI, restriction between the linked inventions similar to that for groups I-VIII and groups IX-XVI will be required. Applicant may anticipate such a restriction requirement by electing one of such a multiplicity of peptides recited in added claims.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for each Group is not required for the other Groups, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

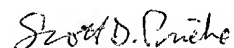
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Scott D. Priebe
Primary Examiner
Art Unit 1632